UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,855	11/13/2000	Brit Kalatz	RDID0006US	8566

7590 06/25/2002

Richard T Knauer
Roche Diagnostics Corporation
9115 Hague Road Building D
P O Box 50457
Indianapolis, IN 46250-0457

EXAMINER	
SHEINBERG, MONIKA B	
ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/711,855	Applicant(s) KALATZ ET AL.	
	Examiner Monika B Sheinberg	Art Unit 1631	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment C

The filing date of the instant application is acknowledged to be: 13 November 2000.

Applicants' arguments, filed March 22, 2002; have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-10, 12 and 32-37 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5, 12, 32, 34, and 35, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejections are maintained as set forth in the previous office action mailed: 13 September 2001. The specification, as filed is not enabling for the method of determining useful values for the evaluation elements as claimed. As such, claims drawn to the use of evaluation elements are not enabled.

1. E: "is a factor" is a non-enabled value due to R_{KH} not being enabled as shown below (claim 2). In addition, the E factor of claim 2 is not limited to the equation in claim 3 for determining E and is in itself, an undefined factor. The specification lacks any guidance for the derivation of E aside from the equation in claim 3. However, the equation of

claim 3 fails to determine E due to the lack of guidance in determining R_{KH} as described below.

2. R_{KH}: the carbohydrate reduction factor value determination is not enabled (claim 3). Applicant argues "it is used to reduce the effect of carbohydrates on blood glucose concentration" (Amendment C, p. 7). However this does not indicate or provide guidance in any fashion how to generate the factor itself. If the factor itself cannot be generated then it cannot be used to reduce an effect. Thus applicants have not provided sufficient guidance in generating the R_{KH} value.
3. F: the value determination of this "empirical factor" is not enabled (claim 3). Applicant argues that F is a factor "close to 0.25 mmol/l/g" (amendment C, p.7). Applicant is improperly reading the limitations of the specification into the claims. In addition, the term "close to" is a relative term that does not provide guidance on how to derive specific parameters for which one of ordinary skill in the art would know to select. How close is close? Thus applicants have not provided sufficient guidance in determining an empirical factor.
4. m: the value of *m* of the summation lacks any definition and thus is not enabled (claim 12). Applicant argues that "*m* indicates the number of carbohydrate consumption" (Amendment C, p. 9). However, this is not indicated within the specification as pointed to on page 8, lines 16-19. In addition the correlation between "a factor that takes into account the consumption of carbohydrates via carbohydrate consumption" and a "number of carbohydrate consumption" as stated by the applicant is unclear; a "number" can be a binary representation of consumption as yes/no, or units of carbohydrates (yet KHj already is indicative of this), and so forth. Thus applicants have not provided sufficient guidance in generating a value for the variable "m".

Thus the instant application fails to provide guidance to one of ordinary skill in the art for generating the above value determinations. They are not disclosed in a manner that one skilled in the art would be enabled to determine without undue experimentation due to the unpredictability of such determinations as: an undefined factor, the degree of closeness, and variable values. The specification lacks clear and concise guidance as to how to practice for

example, the factor determinations for then extrapolating the glucose concentration for the instant invention. Thus applicant's arguments are non-persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12 and 32-37, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to the lack of clarity in the claim language "with consideration for" in line 18. The metes and bounds of that which defines "consideration" is unclear. Claims 2-10, 12 and 32-37 are also indefinite due to their dependency from claim 1.

Claims 5 and 32 remain vague and indefinite in the manner that the term "contains" is used. The lack of clarity is described in the previous office action mailed: September 13, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-10, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Worthington et al (US Patent 8,22,715; 1998).

Worthington et al demonstrates a "diabetes management system" (abstract) that includes an apparatus, method and system that determines a predicted value of blood glucose concentrations at specific times as recited in claim 1. The variable terms recited in claim 1 are described within the reference as well in columns 7-8; all are included as part of a "computer program executed by [a] microprocessor" (column 7, line 43) upon a device that a patient enters relevant information within a prompt field (column 6, line 27-32) of the apparatus display unit. The display unit as per claim 7 is demonstrated by the apparatus "displaying predicted future

blood glucose values" (column 5, lines 53-54); along with a warning audible alert tones (column 6, line 59) upon value determinations outside a "target blood glucose range" (column 5, line 56) as recited in claim 8. The reference teaches the input of various values, including carbohydrate intake units (column 8, lines 13-24) as recited in claim 9. The apparatus itself is a dose control unit in addition to the healthcare center with which apparatus can communicate or transmit dose information for updates, monitoring and so forth (column 11, lines 15-32) as recited in claim 10. The example in column 12 (lines 41-43) demonstrates the use of a 2 hour and 20 minute insulin dose time interval, thus demonstrating the 0.5-5 hour time interval of claim 36 and the 2-4 hour time interval of claim 37. Thus Worthington et al anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-10, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wormington et al (1998) as applied to claims 1, 7-10, 36 and 37 above, and further in view of Conn et al (WO 00/47109; 2000).

Wormington et al does not teach the device to be a microdialysis device for determining actual glucose concentrations.

Conn et al teaches a system made up of devices and methods to determine the "concentration of an analyte present in a biological system" (abstract) as applied to glucose monitoring in diabetic patients. Conn teaches a sensing mechanism or device that performs microdialysis (p. 2, line 15) to determine actual glucose concentration in a sample from "across a skin or mucosal surface" (p. 2, line 2).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to perform the diabetes management system of Wormington et al and further modify the monitoring device to perform microdialysis to determine glucose concentrations as per the teachings of Conn et al. Thus, one of ordinary skill in the art would have been motivated to do the modifications taught by Conn et al due to the advantages of the "painless and automatic approach" (Conn et al, p. 1, lines 12-16) to self-monitoring blood glucose levels.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600
1631

June 23, 2002
Monika B. Sheinberg
Art Unit 1631

MBS